510(k) SUMMARY

APR 29 2014

Sensor Medical Technology LLC
Family of Disposable Lenses

510(k) Owner
Sensor Medical Technology LLC
23175 224th Place SE
Maple Valley, WA 98038
Phone: (425) 358-7381
Contact Person: Louise Culham, Ph.D.

Submission Correspondent
Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245
Facsimile: (978) 824-2541

Date Prepared: February 11, 2014

Trade Name of Device
Sensor Medical Technology Family of Disposable Lenses

Common or Usual Name
Gonioscopic Prisms and Diagnostic Condensing Lens

Classification Name and Regulation
Gonioscopic Prisms
21 CFR 886.1660, HKS
Ophthalmic Panel

Diagnostic Condensing Lens
21 CFR 886.1380, HJL
Ophthalmic Panel

Predicate Devices
Sensor Family of Ophthalmic Lenses (K102371)

Device Description
The Sensor Medical Technology Family of Disposable Lenses is a family of diagnostic and therapeutic contact lenses use for eye examination and therapy of intraocular abnormalities. The Family consists of 14 lenses

including the following: Fundus Lens, 4 Mirror Gonioscopy Lens, Single Mirror Lens, 3 Mirror Lens, Iridotomy Lens, Capsulotomy Lens, Retina 90 Lens, Retina 165 Lens, Retina 180 Lens, Indirect Lenses: 90 D, 78 D, 60 D, 28 D and 20 D.

The Family of Ophthalmic Lenses is designed around the classic Goldmann contact lens. Each model lens is of similar design, but provide different optical elements to provide excellent visualization of the ocular anatomical areas for the particular intended use. When used in conjunction with a slit lamp, the ophthalmic lenses provide a binocular and stereoscopic view of the specific optical region of the eye.

The lenses are provided sterile for single use.

Intended Use / Indications for Use
The Family of Disposable Lenses are a family of diagnostic and therapeutic contact lenses used in the examination of the eye fundus, retina and irido-corneal and vitreous bodies and for the laser therapy of intraocular abnormalities.

Substantial Equivalence
Sensor Medical Technology LLC believes that the Family of Disposable Lenses described in this notification and for use under the conditions of proposed labeling is substantially equivalent to the Sensor LLC Family of Ophthalmic Lenses found to be 510(k) Exempt in K102371. The Family of Disposable Lenses has the same indications for use and similar intended use, similar principles of operation, and similar technological characteristics as the prior version of this product that was found to be 510(k) Exempt. The major difference between the prior version of the product and the version presented in this 510(k) is that the Family of Ophthalmic Lenses described in K102371 were reusable while the lenses described here are provided sterile for single use. Sterility and shelf life testing is provided to demonstrate that the product is as safe and effective as the predicate device and is therefore, substantially equivalent.

Performance Data
Sterilization validation testing was performed which showed that the Family of Disposable Lenses met the sterilization requirements specified in the sterilization validation protocol. Shelf life testing was performed which confirmed a 24 month shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

Sensor Medical Technology, LLC
% Ms. Maureen O'Connell
Regulatory Consultant
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K140368
Trade/Device Name: Sensor Medical Technology LLC Family of Disposable Lenses
Regulation Number: 21 CFR 886.1660
Regulation Name: Gonioscopic Prisms
Regulatory Class: Class I
Product Code: HKS
Dated: March 4, 2014
Received: March 5, 2014

Dear Ms. O'Connell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140368

Device Name
Sensor Medical Technology Family of Disposable Lenses

Indications for Use *(Describe)*
The Sensor Medical Technology Family of Disposable Lenses are a family of diagnostic and therapeutic contact lenses used in the examination of the eye fundus, retina and irido-corneal and vitreous bodies and for the laser therapy of intraocular abnormalities.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Leonid Livshitz -S
2014.04.25 14:21:08 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."